K063374

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
Grace Medical Partial Ossicular Replacement Prostheses

DEC - 6 2006

Trade Name:	The family of Grace Medical Nitinol Partial Ossicular Replacement Prostheses consists of:

- Nitinol Locking Incudo-Stapedial Joint
- Nitinol Locking Angular Piston
- Nitinol Locking Piston
- Nitinol Locking Malleus Piston
- Nitinol Locking PORP
- Footplate Shoe

Common Name:	Partial Ossicular Replacement Prostheses
Classification Name:	Partial Ossicular Replacement Prostheses (CFR 21 § 874.3450)

Official Contact:	Jeff Cobb Vice President of Regulatory Affairs & Quality Grace Medical, Inc. 8500 Wolf Lake Drive, Suite 110 Memphis, TN 38133
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Date Prepared:	November 8, 2006

Predicate Devices

1) SMart ISJ Prosthesis manufactured by Gyrus ENT LLC and cleared via 510(k) No. K033554.
2) SMart Piston manufactured by Gyrus ENT LLC and cleared via 510(k) No. K003214.
3) Angular Prosthesis (Plester) manufactured by Heinz Kurz GmbH Medizintechnik and cleared via 510(k) No. K972492.
4) CliP Piston MVP manufactured by Heinz Kurz GmbH Medizintechnik and cleared via 510(k) No. K042503.
5) CliP Piston aWengen manufactured by Heinz Kurz GmbH Medizintechnik and cleared via 510(k) No. K021479.
6) Adjustable and Fixed-Length PORPs manufactured by Grace Medical, Inc. and cleared via 510(k) No. K061853.
7) Partial Ossicular Replacement Prosthesis manufactured by Grace Medical, Inc. and cleared via 510(k) K972815.

Intended Use – The Grace Medical Partial Ossicular Replacement Prostheses have the same primary intended use as the predicate devices.

An ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear. Ossicular replacement prostheses are indicated for the functional restoration of the ossicular chain when a conductive hearing loss is present. Indications for use include:

(a) Chronic middle ear disease,
(b) Otosclerosis,
(c) Congenital fixation of the stapes,
(d) Secondary surgical intervention to correct for a significant and persistent conductive hearing loss from prior otologic surgery, and
(e) Surgically correctible injury to the middle ear from trauma.

Material(s) – The Grace Medical Partial Ossicular Replacement Prostheses are manufactured from the same materials as the predicate devices:

(i) Nitinol (ASTM F2063-05)
(ii) Unalloyed titanium (ASTM F67)
(iii) Titanium alloy (ASTM F136)
(iv) Hydroxylapatite (ASTM F1185)
(v) Fluoroplastic (USP Class VI for plastics, ASTM D1710 and ASTM F754)
(vi) Medical grade silicone

Comparison Charts

NITINOL LOCKING INCUDO-STAPEDIAL JOINT

	Nitinol Locking Incudo-Stapedial Joint	SMart ISJ (Gyrus)	SMart Piston (Gyrus)	Angular Prosthesis (Kurz)	Similarities or Differences
Intended Use	An ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear.	Same	Same	Same	Same
Material(s)	Nitinol	Nitinol	Nitinol Fluoroplastic	Titanium	Substantially Equivalent
Method of Attachment	Manual or Heat Crimp-Assist	Same	Same	Manual	Same as SMart ISJ and SMart Piston. Different than but SE to Kurz Angular Prosthesis.
How Supplied	Sterile	Sterile	Sterile	Sterile	Same

NITINOL LOCKING ANGULAR PISTON

	Nitinol Locking Angular Piston	SMart ISJ (Gyrus)	SMart Piston (Gyrus)	Angular Piston (Kurz)	Similarities or Differences
Intended Use	An ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear.	Same	Same	Same	Same
Material(s)	Nitinol Titanium	Nitinol	Nitinol Fluoroplastic	Titanium	Substantially Equivalent
Lengths	3.0mm to 9.0mm	n/a	3.0mm to 6.0mm	4.25mm to 4.75mm	Substantially Equivalent
How Supplied	Sterile	Sterile	Sterile	Sterile	Same

NITINOL LOCKING PISTON

	Nitinol Locking Piston	SMart ISJ (Gyrus)	SMart Piston (Gyrus)	Angular Piston (Kurz)	Similarities or Differences
Intended Use	An ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear.	Same	Same	Same	Same
Material(s)	Nitinol Titanium Fluoroplastic	Nitinol	Nitinol Fluoroplastic	Titanium	Substantially Equivalent
Lengths	3.0mm to 9.0mm	n/a	3.0mm to 6.0mm	4.25mm to 4.75mm	Substantially Equivalent
How Supplied	Sterile	Sterile	Sterile	Sterile	Same

NITINOL LOCKING MALLEUS PISTON

	Nitinol Locking Malleus Piston	CliP Piston MVP (Kurz)	CliP Piston aWengen (Kurz)	Similarities or Differences
Intended Use	An ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear.	Same	Same	Same
Material(s)	Nitinol Titanium Fluoroplastic	Titanium	Titanium	Substantially Equivalent
Lengths	3.0mm – 9.0mm	5.00mm – 6.25mm	4.0mm – 5.5mm	Substantially Equivalent
How Supplied	Sterile	Sterile	Sterile	Same

NITINOL LOCKING PORP

	Nitinol Locking PORP	SMart ISJ (Gyrus)	SMart Piston (Gyrus)	Grace Adjustable and Fixed-length PORPs	Similarities or Differences
Intended Use	An ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear.	Same	Same	Same	Same
Shaft Material(s)	Nitinol Titanium Silicone (sleeve on adjustable models)	Nitinol	Nitinol Fluoroplastic	Titanium Silicone (sleeve on adjustable models)	Substantially Equivalent
Head Material(s)	Titanium Hydroxylapatite	No head	No head	Titanium Hydroxylapatite	Same
Lengths	Fixed Sizes: 0.5mm to 9.0mm Adjustable model – Trimmed intraoperatively to length	n/a	3.0mm to 6.0mm	Fixed Sizes: 0.5mm to 9.0mm Adjustable model – Trimmed intraoperatively to length	Substantially Equivalent
How Supplied	Sterile	Sterile	Sterile	Sterile	Same

FOOTPLATE SHOE

	Footplate Shoe	Grace HA Footplate Shoe K972815	Similarities or Differences
Intended Use	An ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear.	Same	Same
Material(s)	Nitinol Titanium Hydroxylapatite	Hydroxylpaptite	Substantially Equivalent
Accommodates Shafts with Diameters:	0.3mm to 1.07mm	1.07mm	Substantially Equivalent
How Supplied	Sterile	Sterile	Same

Differences between the Grace Medical Modified Partial Ossicular Replacement Prostheses and the predicate devices should not affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Grace Medical, Inc.
c/o Jeff Cobb
Regulatory Affairs & Quality
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Suite 110
Memphis, TN

DEC - 6 2006

Re: K063374
Trade/Device Name: Partial Ossicular Replacement Prostheses, Nitinol Incudo-Stapedial Joint, Nitinol Angular Piston, Nitinol Piston, Nitinol Malleus Piston, Nitinol PORP and Footplate Shoe
Regulation Number: 21 CFR 874.3450
Regulation Name: Partial ossicular replacement prosthesis
Regulatory Class: Class II
Product Code: ETB
Dated: November 8, 2006
Received: November 8, 2006

Dear Mr. Cobb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K063374

Device Name: Partial Ossicular Replacement Prostheses including: Nitinol Incudo-Stapedial Joint, Nitinol Angular Piston, Nitinol Piston, Nitinol Malleus Piston, Nitinol PORP, and Footplate Shoe

Indications for Use:

An ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear. Ossicular replacement prostheses are indicated for the functional restoration of the ossicular chain when a conductive hearing loss is present. Indications for use include:

(a) Chronic middle ear disease,
(b) Otosclerosis,
(c) Congenital fixation of the stapes,
(d) Secondary surgical intervention to correct for a significant and persistent conductive hearing loss from prior otologic surgery, and
(e) Surgically correctible injury to the middle ear from trauma.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2/96)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K063374